

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MAR 8 1996

Dr. Christopher E. Flick
Director, Research
Dekalb Genetics Corporation
Discovery Research
62 Maritime Drive
Mystic, CT 06355-1958

Dear Dr. Flick:

This is in regard to Dekalb's consultation with the Food and Drug Administration (FDA) (Center for Veterinary Medicine and Center for Food Safety and Applied Nutrition) on genetically modified corn, specifically transformation event DLL25. According to Dekalb, transformation event DLL25 is modified to express the *bar* gene isolated from *Streptomyces hygroscopicus*. The *bar* gene encodes the phosphinothricin acetyltransferase (PAT) protein, which reportedly confers tolerance to the herbicide, glufosinate ammonium.

In July 1995, Dekalb wrote to FDA to discuss the proposed safety and nutritional assessment of corn containing transformation event DLL25. As part of bringing the consultation regarding this product to closure, Dekalb submitted a summary assessment of corn containing transformation event DLL25 on November 17, 1995.

These communications informed FDA of the steps taken by Dekalb to ensure that this product complies with the legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment Dekalb has conducted, it is our understanding that Dekalb has concluded that corn grain, fodder, and silage derived from the new variety, are not materially different in composition, safety, and other relevant parameters from corn grain, fodder, and silage currently on the market and that the genetically modified corn does not raise issues that would require premarket review or approval by FDA. All materials relevant to this notification have been placed in a file designated BNF0028. This file will be maintained in the Office of Premarket Approval.

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Based on the information Dekalb has presented, we have no further questions concerning grain, fodder, and silage from event DLL25 corn at this time. However, as you are aware, it is Dekalb's continued responsibility to ensure that foods marketed by the firm are safe, wholesome and in compliance with all applicable legal and regulatory requirements.

Sincerely,

/s/

Alan M. Rulis, Ph.D.
Director
Office of Premarket Approval
Center for Food Safety and
Applied Nutrition

cc: HFS-200 HFS-205 HFS-226 HFS-235 HFS-246 HFS-247
HFS-13 HFS-144 HFV-200 HFV-221 HFV-226
BNF0028 HFS-206